

REMARKS

Claims 1-8 are presently pending. Claims 1, 3, 5, 6 and 8 have been amended herein. Claim 2 has been canceled and new claim 9-11 have been added. Claims 1, 3, 5, 6 and 8 have been amended herein. The amendments and new claims are supported throughout the specification, for example, at page 24, lines 27-30; page 32, line 16 to page 33, line 9; and Example 1. The specification has been amended to update the priority information. No new matter has been introduced by way of the amendments and entry is respectfully requested. Upon entry of the amendments, claims 1, 3-11 will be pending and under consideration.

Regarding the Claim Objections

Applicants have corrected the errors in claims 1 and 5 as pointed out at page 3 of the current Office Action. Accordingly, withdrawal of the objection is respectfully requested.

Regarding 35 U.S.C. § 112, Second Paragraph

Applicants respectfully traverse the rejection of claims 1-8 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants respectfully submit that the amendments made herein render this rejection moot.

Claims 1-8 are allegedly incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP 2172.01. The Action asserts that the method steps should minimally recite contacting, detection and correlation steps. Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, e.g., *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); and *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999) (district court failed to consider the knowledge of one skilled in the art when interpreting the patent disclosure). Applicants respectfully submit that claim 1, as amended, is clear and definite to one possessing the ordinary level of skill in the pertinent art at the time the

invention was made and in light of the specification. The skilled person would understand with clarity that the steps of contacting, detection and correlation are present in the claim 1. There is no authority and no language in the MPEP that requires that the terms “contacting, detection and correlation” are recited in a method claim. Rather, the requirement is that the skilled person would appreciate that the steps are encompassed in the method as claimed and not consider essential steps lacking.

It is also asserted to be unclear how the IL-16 and RANTES relate to T cell activation and how T cell activation relates to disease. Applicants respectfully submit that the amendments made herein render this rejection moot. The reference to “T cell activation” was a typographical error and should read “fibroblast activation” as is taught throughout the specification. Accordingly, claim 3 has been amended to reference “fibroblast activation,” thereby rendering moot the rejection.

The Action further notes that claim 1 recites “obtaining a biological sample” from a patient, but not that the disease specific IgG is present within that sample. Applicants respectfully submit that claim 1 has been amended to recite the claimed method with greater clarity. In addition, it is respectfully pointed out that the object is to detect presence of the disease such that it is not known at the outset of practicing the method whether disease specific IgGs are present in the sample nor is such knowledge a prerequisite for practicing the claimed method.

The Action also states that, while claims 2-6 require T cells to perform the methods, the source of the T cells is unclear. A amended, claims 2-5 no longer recite “T-cells,” rendering this rejection moot. With regard to claim 6, an amendment has been made to indicate that T-cell migration is determined on T –cells in the biological sample.

Regarding 35 U.S.C. § 112, First Paragraph (Enablement)

Applicants respectfully traverse the rejection of claims 1-8 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to practice the invention.

Applicant respectfully maintains that the specification enables the full scope of the claimed invention for the reasons that follow. Applicants further submit that this rejection has been rendered moot by the amendments made herein.

The Action asserts that Applicants do not disclose, nor does the art support, a method of detecting Graves disease arthritis comprising measuring the binding of disease specific IgG with IGF-1. Claim 1 has been amended to replace "IGF-1" with "IGF-1 receptor," rendering this ground of rejection moot.

The Action asserts that the term "determination of T-cell activation" is broad and encompasses both the expression and down-regulation of any cell surface marker, cytokine, protein, DNA, RNA or other factor associated with the stimulation of a particular T cell, including as yet undiscovered proteins and factors. It is further alleged that determining "T cell activation" to diagnose disease is not supported by the disclosure. Claim 3 has been corrected herein to recite activation of fibroblasts rather than T-cells, rendering this ground of rejection moot.

The Action further asserts that the specification does not support the recitation of measuring "a chemical marker expressed by activated T cells, including IL-16 and RANTES, but concedes that the specification teaches measuring IL-16 and RANTES released from fibroblasts. As amended, the claims correctly recite that the chemical marker is released by activated fibroblasts.

Based on the above amendments and remarks, Applicant respectfully submit that the specification enables the full scope of the claimed invention. Accordingly, Applicants respectfully request removal of the rejection of claims 1-8 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to practice the invention.

Regarding 35 U.S.C. § 112, First Paragraph (Written Description)

Applicants respectfully traverse the rejection of claims 1-8 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, had possession of the claimed invention at the time the application was filed. Applicants respectfully submit that the specification provides sufficient written description for claims 1-8 as amended herein. The amendments are described above. It is submitted that the above amendments render the rejection moot and removal of the rejection is respectfully requested.

CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned attorney if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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